



Our Ref.:

Date :

Urgent Field Safety Notice

Indiana Ophthalmics LLP is issuing urgent Field Safety notice to inform about the potential risk of microbial contamination in Carbomer eye Gel

Commercial name of the affected product: Carbomer Eye Gel (AACARB, AACOMER eye gel & PUROPTICS eye gel)



FSCA : 001/2023

Type of action: To withhold the distribution and recall the product from the market.

Date: 22/11/2023

Attention: Patients / Retailers / Healthcare Professionals / Distributors

Details on affected devices/ products:

Brand Name	Batch No.	Expiry Date	Pack Size	Product Photographs
AaCarb	3H07	07/2025	1 X 10 gm	
AaCarb	3H08	07/2025	1 X 10 gm	
AaCarb	3I02	08/2025	1 X 10 gm	
AaCarb	3I03	08/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3J23	09/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3J24	09/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3K01	10/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3K02	10/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H02	07/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H03	07/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H04	07/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H05	07/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H06	07/2025	1 X 10 gm	
Puroptics Eye Gel	3H09	07/2025	1 X 10 gm	
Puroptics Eye Gel	3H10	07/2025	1 X 10 gm	
Puroptics Eye Gel	3H11	07/2025	1 X 10 gm	
Puroptics Eye Gel	3J07	09/2025	1 X 10 gm	
Puroptics Eye Gel	3J08	09/2025	1 X 10 gm	
Puroptics Eye Gel	3J09	09/2025	1 X 10 gm	



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Description of the problem:

There is a potential risk of microbial contamination (*Burkholderia cenocepacia*) in the affected eye gels. This potential link with carbomer eye gel was identified during an investigation by public health authorities and the investigation is still ongoing. There is a potential risk of infection if the affected eye gel is used. The risk is higher in people with an impaired immune system.

Advise on action to be taken by the patients and customers:

- Stop using the products from the affected batches immediately and return the product to the place of purchase.
- Contact your doctor or pharmacist for advice on suitable alternatives.
- If your eye symptoms worsen or you are worried about your health, contact a healthcare professional urgently. Tell them you have been using a recalled eye gel.

Advise on action to be taken by the healthcare setting, pharmacies, retailers, wholesalers, distributors:

- Stop supplying the affected batches immediately, quarantine all remaining stock and return it to the supplier using the supplier approved process. The details of supplier / distributor for each product are provided below.
- Where possible, contact patients/customers who have been dispensed or purchased any of the affected batches and ask them to return the product.
- Healthcare professionals who are contacted for advice on replacement products should consider appropriate review of patient's health.

Further Information:

Contact the below concerned distributors for the return of products:

AACARB – Trion Pharma UK, Unit 7, Kimpton Business Link, 40 Kimpton road, Sutton, Surrey SM3 9QP, UK

info@trionpharma.co.uk, +447859809049

AACOMER Eye Gel – Essential Healthcare Ltd., 249 – Ongar road, Brentwood, Essex, CM15 9DZ, UK.

Info@essential-healthcare.co.uk, +441277286199

PUROPTICS Eye Gel – Biovantic Pharma Ltd., Kemp house, 160 City Road, London. EC1V 2NX, UK

anir@biovanticpharma.co.uk, +447791913552



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Transmission of this Field Safety Notice:

This notice needs to be passed on all those who needs to be aware about the potentially affected device.

Contact reference person for further information:

For more information contact

Indiana Ophthalmics LLP, 135, 136, 137 – GIDC Estate, Wadhwan, Gujarat, India

indianaophthalmics@yahoo.co.in

+912752241554 / +912752243939

Recipient of the device recall should bring it to the attention of all relevant contacts by copy of this notice.

